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to enrolled recipients, under contract with the Medical agency and on the basis of prepaid capitation fees, but is not subject to requirements in section 1903(m)(2)(A) of the Act.

Private nonmedical institution means an institution (such as a child-care facility or a maternity home) that—

(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;

(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and

(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

Professional management service or consultant firm means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

Provisional status HMO means an HMO that the State agency has determined is a provisional status Federally qualified HMO because more than 90 days have elapsed since the HMO applied to the PHS for Federal qualification and the PHS has not made a final determination. The provisional status continues until the PHS makes the final determination or the contract with the Medicaid agency is terminated, whichever occurs first.

Risk or underwriting risk means the possibility that a contractor may incur a loss because the cost of providing services may exceed the payments made by the agency to the contractor for services covered under the contract.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 52 FR 22322, June 11, 1987; 55 FR 51295, Dec. 13, 1990]

EFFECTIVE DATE NOTE: At 66 FR 6403, Jan. 19, 2001, § 434.2 was amended by removing the definitions of “Capitation fee”, “Clinical laboratory”, “Contractor”, “Enrolled recipient”, “Federally qualified HMO”, “Health insuring organization (HIO)”, “Health maintenance organization (HMO)”, “Nonrisk”, “Prepaid health plan (PHP)”, “provisional status HMO”, and “risk or underwriting risk”, effective April 19, 2001. At 66 FR 11546, Feb. 26, 2001 the effective date was delayed until June 18, 2001, at 66 FR 32776, June 18,

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2001 it was furthered delayed until Aug. 17, 2001, and at 66 FR 43090, Aug. 17, 2001 it was furthered delayed until Aug. 16, 2002.

§ 434.4 State plan requirement.

If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

§ 434.6 General requirements for all contracts and subcontracts.

(a) *Contracts.* All contracts under this part must—

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74, appendix G;

(2) Identify the population covered by the contract;

(3) Specify any procedures for enrollment or reenrollment of the covered population;

(4) Specify the amount, duration, and scope of medical services to be provided or paid for;

(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;

(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(8) Provide that the contractor safeguards information about recipients as required by part 431, subpart F of this chapter;

(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in part 433, subpart D of this chapter;

(10) Specify which functions may be subcontracted; and

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(b) *Subcontracts.* All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

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(c) *Continued responsibility of contractor.* No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

EFFECTIVE DATE NOTE: At 66 FR 6403, Jan. 19, 2001, § 434.6 was amended in paragraph (a)(1) by removing “Appendix G”, effective April 19, 2001. At 66 FR 11546, Feb. 26, 2001 the effective date was delayed until June 18, 2001, at 66 FR 32776, June 18, 2001 it was furthered delayed until Aug. 17, 2001, and at 66 FR 43090, Aug. 17, 2001 it was furthered delayed until Aug. 16, 2002.

Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

§ 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

- (a) Meet the requirements of § 434.6;
- (b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—
 - (1) Computer programs;
 - (2) Data files;
 - (3) User and operation manuals, and other documentation;
 - (4) System and program documentation; and
 - (5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;
- (c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:
 - (1) Purchasing the material; or
 - (2) Purchasing the use of the material through leasing or other means; and
- (d) State that payment to providers will be made in accordance with part 447 of this chapter.

§ 434.12 Contracts with private non-medical institutions.

Contracts with private nonmedical institutions must—

- (a) Meet the requirements of § 434.6;
- (b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement re-

quirements prescribed in part 447 of this chapter; and

- (c) Specify when the capitation fee must be paid.

§ 434.14 [Reserved]

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

EFFECTIVE DATE NOTE: At 66 FR 6403, Jan. 19, 2001, subpart C consisting of §§ 434.20 through 434.38 was removed and reserved, effective April 19, 2001. At 66 FR 11546, Feb. 26, 2001 the effective date was delayed until June 18, 2001, at 66 FR 32776, June 18, 2001 it was furthered delayed until Aug. 17, 2001, and at 66 FR 43090, Aug. 17, 2001 it was furthered delayed until Aug. 16, 2002.

GENERAL REQUIREMENTS

§ 434.20 Basic rules.

(a) *Entities eligible for risk contracts for services specified in § 434.21.* A Medicaid agency may enter into a risk contract for the scope of services specified in § 434.21, only with an entity that—

- (1) Is a Federally qualified HMO, including a provisional status Federally qualified HMO;
- (2) Meets the State plan's definition of an HMO, as specified in paragraph (c) of this section;
- (3) Is one of several entities identified in section 1903(m)(2)(B) (i), (ii) and (iii) of the Act, and considered as PHPs;
- (4) Is one of certain Community, Migrant and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B), these entities are subject to the regulations governing HMOs under this part, with the exception of the requirements of section 1903(m)(2)(A) (i) and (ii) of the Act; or
- (5) Is an HIO that arranges for services and becomes operational before January 1, 1986.

(b) *Entities eligible for other kinds of contracts.* A Medicaid agency may enter into a nonrisk contract, or a risk contract for a scope of services other than the scope specified in § 434.21(b), with any of the entities identified in paragraph (a) of this section, or with any other PHP.